REMARKS

I. INTRODUCTION

Claims 122 and 123 have been amended as provided herein above to remove minor informalities therefrom, and clarify the subject matter recited therein and address the Examiner's comments. Claims 1-121 have previously been cancelled, without prejudice. Claims 122-143 are currently under consideration in the above-identified application.

Provided above, please find a claim listing indicating the current amendments to claims 122 and 123, and the status of the other claims so as to comply with the requirements set forth in 37 C.F.R. §1.121. Applicants reserve the right to pursue patentability of these cancelled claims and/or other claims in any continuing application claiming priority from the above-identified application, and any application for which this application claims priority. It is respectfully submitted that no new matter has been added. Support for the amendments to claims 122 and 123 can be found in the originally-filed application, including the specification, drawings and/or claims thereof. (See, e.g., Substitute Specification of the above-identified application, paras. [0059] and [0060], and Figures 10A and 10B).

II. REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN

Claims 122-143 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Patent No. 7,311,731 to Lesniak et al. (hereinafter the "Lesniak Patent"). Applicants respectfully assert that the Lesniak Patent does not disclose the subject matter recited in amended independent claims 122 and 123 for at least the reasons provided herein below.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

The Lesniak Patent "relates generally to medical devices and therapeutic methods for their use in the field of interventional cardiology and cardiac surgery, and more specifically to a catheter-based, mini-thoracotomy, or open chest systems to stiffen a myocardial infarction area, to shrink the myocardial infarct region, and/or to reduce wall motion in a peri-infarct and/or infarct region of a heart. (Lesniak Patent, col. 1, lns. 16-22).

Amended independent claim 122 recites a method of reversing cardiac remodeling, comprising: **delivering a material through an external tissue portion of the heart and into a region of tissue of the heart** so as to displace a portion of the region of tissue inward and toward the center line of the ventricular cavity, thereby **normalizing cardiac geometry**. Amended independent claim 123 recites a method for reducing regurgitation of an atrioventricular valve of a heart, comprising: **delivering a material through an external portion of muscle wall of the heart and into a muscle wall region of the heart proximate the papillary muscle**, the material displacing a portion of said muscle wall region inward and toward the center line of the ventricular cavity of the heart so as to **normalize papillary muscle geometry** and improve leaflet coaptation.

It is respectfully asserted that the Lesniak Patent **fails** to disclose at least that the material is delivered **through an external tissue portion of the heart and into a region of tissue of the heart**, *much less* where the material is delivered so as to displace a portion of the

region of tissue inward and toward the center line of the ventricular cavity, thereby **normalizing cardiac geometry**, as explicitly recited in amended independent claim 122. Further, Applicants respectfully assert that the Lesniak Patent **fails** to disclose at least that the material is delivered **through an external portion of muscle wall of the heart and into a muscle wall region of the heart proximate the papillary muscle**, *much less* where the material displaces a portion of the muscle wall region inward and toward the center line of the ventricular cavity of the heart so as to **normalize papillary muscle geometry** and improve leaflet coaptation, as explicitly recited in amended independent claim 123.

In the Office Action, the Examiner contends that the Lesniak Patent allegedly "teaches delivering a material to different areas within the heart tissue, such as papillary muscle ... to physically modify or alter the geometry to treat valve regurgitation." (Office Action, p. 2). The Examiner then points to the Abstract, col. 17, ln. 33 – col. 18., ln. 45, and Figs. 13-16 and 25a-25d of the Lesniak Patent in support of this contention.

However, the sections of the Lesniak Patent on which the Examiner relies describes placing devices and materials "either through a percutaneous, mini-thoracotomy, or open-chest approach." (Lesniak Patent, col. 17, lns. 4-41 and col. 18, ln. 32-33). "For the percutaneous approach, a catheter is positioned in the left ventricle, placed against the endocardial surface, and the infarct tissue identified." (*Id.*, col. 17, lns. 42-45 and col. 18, lns. 36-38). For the delivery of a device, such "device is inserted into the myocardium." (*Id.*, col. 17, lns. 45-46). For the delivery of material, "material is directly injected into the infarct tissue, or is injected into the coronary artery or vein." (*Id.*, col. 18, lns. 33-35). Further, the Lesniak Patent describes that "[f]or an open chest approach, a small needle can be inserted into the infarct tissue

and the material is injected [and that a] similar procedure is used for a mini-thoracotomy approach." (*Id.*, col. 18, lns. 46-48).

Accordingly, the Lesniak Patent certainly does not disclose that the material is delivered through an *external tissue portion of the heart* and into a region of tissue of the heart, as explicitly recited in amended independent claim 122, or that the material is delivered through an *external portion of muscle wall of the heart* and into a muscle wall region of the heart proximate the papillary muscle, as explicitly recited in amended independent claim 123.

Rather, in contrast, as described herein above, the Lesniak Patent specifically describes that the "material is *directly injected* into the infarct tissue, or is injected into the coronary artery or vein." Clearly, a procedure in which material is *directly* injected is certainly not at all equivalent to a procedure in which material is delivered *through* an external tissue portion of the heart and *into* a region of tissue of the heart, as recited in amended independent claims 122 and 123 of the above-identified application.

Further, Applicants respectfully assert that injecting material into the coronary artery or vein is also not equivalent to a procedure in which material is delivered *through* an external tissue portion of the heart and *into* a region of tissue of the heart. Indeed, the coronary artery or vein is not even an external tissue portion of the heart, as explicitly recited in amended independent claim 122, *much less* an external portion of muscle wall of the heart, as explicitly recited in amended independent claim 123. Moreover, injecting the material into the coronary artery or vein as described in the Lesniak Patent certainly does not provide for the material being delivered so as to displace a portion of the region of tissue *inward and toward the center line of the ventricular cavity*, thereby normalizing cardiac geometry, as explicitly recited in amended

independent claim 122, *much less* to displace a portion of the muscle wall region *inward and toward the center line of the ventricular cavity* of the heart so as to normalize papillary muscle geometry and improve leaflet coaptation, as explicitly recited in amended independent claim 123. Rather, injecting the material into the coronary artery or vein as described in the Lasniak Patent could displace a portion of the region of tissue *outward and away from the center line of the ventricular cavity*, and thereby have an opposite effect to that recited in amended independent claims 122 and 123.

Accordingly, Applicants respectfully assert that the Lesniak Patent fails to disclose the subject matter recited in amended independent claims 122 and 123 of the above-identified application, and the claims which depend therefrom.

Therefore, for at least the reasons indicated herein above, Applicants respectfully assert that the rejection under 35 U.S.C. § 102(e) of amended independent claims 122 and 123, and claims 124-143 which depend therefrom, as applicable, as allegedly being anticipated by the Lesniak Patent should be withdrawn.

III. CONCLUSION

In light of the foregoing, Applicants respectfully assert that all pending claims 122-143 are in condition for allowance. Prompt consideration, reconsideration and allowance of all of the claims of the present application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided below.

Respectfully submitted,

Date: December 17, 2010

By: 

Gary Abelev
Patent Office Reg. No. 40,479

Randall M. Berman
Patent Office Reg. No. 61,609

DORSEY & WHITNEY, L.L.P.
250 Park Avenue
New York, New York 10177

Attorney(s) for Applicant(s)
(212) 415-9371